



**UNITED STATES DEPARTMENT OF COMMERCE  
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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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33M1

M	910022
EXAMINER	

GUTOWSKI, A

ART UNIT	PAPER NUMBER
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3306

DATE MAILED:

03/31/93

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☒ Responsive to communication filed on 12/28/92 ☒ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), \_\_\_\_\_ days from the date of this letter.  
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

**Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:**

- |   |  |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited by Examiner, PTO-892.        | 2. <input type="checkbox"/> Notice re Patent Drawing, PTO-948.                   |
| 3. <input type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449.             | 4. <input type="checkbox"/> Notice of Informal Patent Application, Form PTO-152. |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474. | 6. <input type="checkbox"/> _____  |

**Part II SUMMARY OF ACTION**

1. ☒ Claims 16-31 are pending in the application.  
Of the above, claims \_\_\_\_\_ are withdrawn from consideration.
2. ☐ Claims \_\_\_\_\_ have been cancelled.
3. ☐ Claims \_\_\_\_\_ are allowed.
4. ☒ Claims 16-31 are rejected.
5. ☐ Claims \_\_\_\_\_ are objected to.
6. ☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on \_\_\_\_\_. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable. ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on \_\_\_\_\_, has (have) been ☐ approved by the examiner. ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed on \_\_\_\_\_, has been ☐ approved. ☐ disapproved (see explanation).
12. ☐ Acknowledgment is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received  
☐ been filed in parent application, serial no. \_\_\_\_\_; filed on \_\_\_\_\_.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 16-18, 22-25 and 28-31 are rejected under 35 U.S.C. § 102(b) as being anticipated by Jang. Jang teaches the catheter as claimed. Note balloon 80 which is connected to the tubing by fusion bonds next to the tapered regions as disclosed on lines 47-51 of column 14. Note in particular that Jang teaches conventional laser bonding. The tapered regions of the Jang catheter would inherently be substantially free of crystallization to allow for proper balloon inflation and deflation (in particular if the disclosed conventional laser bonding is used). The fusion bonds on the neck regions would inherently be immediately adjacent (less than .010 to .030 inches) of the balloon tapered regions to prevent inflation of the neck regions upon balloon inflation.

Claims 16-18, 22, 24-26, 28, 29 and 31 are rejected under 35 U.S.C. § 102(b) as being anticipated by either Gahara et al or Wolvek et al.

Gahara et al teach the catheter as claimed. Note figure 5, lines 47-51 of column 4 and lines 26-29 of column 5.

Wolvek et al teach the catheter as claimed. Note lines 7, 8

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and 13-18 of column 6.

Both the Gahara et al balloon and the Wolvek balloon would inherently have the fusion bonds within less than .010 inches to .030 inches of the balloon tapered regions to prevent inflation of the neck regions of the balloon. These balloons would further inherently have tapered regions substantially free of crystallization to allow for proper balloon inflation and deflation.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 19-21 and 27 are rejected under 35 U.S.C. § 103 as being unpatentable over Jang. Jang teaches the catheter substantially. It is considered a conventional design expedient in the art to minimize the use of material to reduce the cost of a balloon catheter. One of ordinary skill in the art would

provide a neck region and corresponding band on the Jang catheter which is within the claimed range to reduce balloon catheter cost. Note that Jang teaches using laser bonding, which as admitted by applicant is capable of a bond within the claimed dimensions. In view of this above, it would have been obvious to modify the Jang catheter with a bond length within the claim range.

Applicant's arguments filed December 28, 1992 have been fully considered but they are not deemed to be persuasive.

The examiner notes that applicant has failed to provide a showing in the form of factual evidence such as affidavits, declarations and/or test data to rebut the examiner's argument of inherency or to provide a showing of unexpected results.

Applicant initially alleges that crystallization is the "inevitable result" in fusion bonding. The examiner disagrees with applicant's statement. Crystallization of a polymer requires cooling a polymer at a sufficiently slow rate from a temperature above the melting point temperature of the polymer to a temperature below the melting point temperature. If a polymer is rapidly cooled from a temperature above the melting point to a temperature below the melting point, crystallization does not occur. Contrary to applicant's statement, crystallization is not the inevitable result of fusion bonding unless the cooling rate of the polymer is sufficiently slow.

A polymeric crystallization process initially requires heating a polymer above the melting point (melting a solid polymer into a liquid polymer) and then cooling the polymer at a sufficiently slow rate to form a solid polymer with crystallization. Crystallization requires a polymer to be initially heated above the melting point temperature and therefore converted from a solid phase to a liquid phase. During fusion bonding of a polymer balloon to a polymer catheter, the temperature of the balloon is raised above the balloon polymer melting point temperature only at the neck region of the balloon to fuse (i.e. melt together) the balloon polymer and catheter polymer. In a conventional heat fusion process, such as is discussed in Jang, Gahara et al or Wolvek et al, the temperature at the taper portions of the balloon is conventionally never raised above the melting point. Raising the temperature of a balloon tapered portion above the melting point would cause the polymeric material in this balloon area to melt, and accordingly the balloon tapered portion would lose the structure integrity and shape required for proper balloon inflation. The balloon tapered portions of the balloons taught by the references would inherently be substantially free of crystallization, because these tapered portions would not be heated above the melting temperature of the balloon polymer in a conventional fusion process to properly form a catheter balloon.

In particular, the conventional laser bonding of balloon 80, as mentioned on lines 47-50 of Jang, would inherently provide the claimed bond, because conventional laser bonding allows for accurate focusing of heat and provides for extremely close manufacturing tolerances. Applicant has failed to provide any factual evidence to support applicant's opinion that a bond obtained by applicant's laser bonding method is patentably distinguishable from a bond obtained from a conventional laser bonding method.

In regards to applicant's arguments concerning claims 17 and 18 and the Jang rejection note that balloon 80 shown in figure 11 of Jang clearly teaches the claimed neck inner diameters substantially equal to the catheter tubing outer diameters, and annular bonds.

Applicant argues that the balloon and tubing of the Jang catheter are formed from the same material. The examiner disagrees and directs applicant's attention to lines 22-25 and lines 43-47 in column 14 which disclose fabricating balloon 80 from a material which is different from the tubing.

In regard, to applicant's remarks concerning the Jang rejection of claims 24 and 25, method of manufacture limitations in article claims are given very little patentable weight absent distinguishable structure.

In regard to applicant's remarks concerning the Gahara et al

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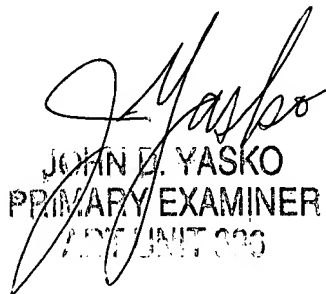
reference and Wolvek et al reference, applicant has failed to provide factual evidence to support the assertion that these references do not teach the claimed bond.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a). The practice of automatically extending the shortened statutory period an additional month upon the filing of a timely first response to a final rejection has been discontinued by the Office. See 1021 TMOG 35.

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Any inquiry concerning this communication should be directed to Anthony Gutowski at telephone number (703) 308-2980.

  
A. Gutowski/dh  
March 26, 1993

  
JOHN E. YASKO  
PRIMARY EXAMINER  
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